



A critical review of the neurological effects of invasive cardiac procedures:

DO WE NEED TO DO BETTER?

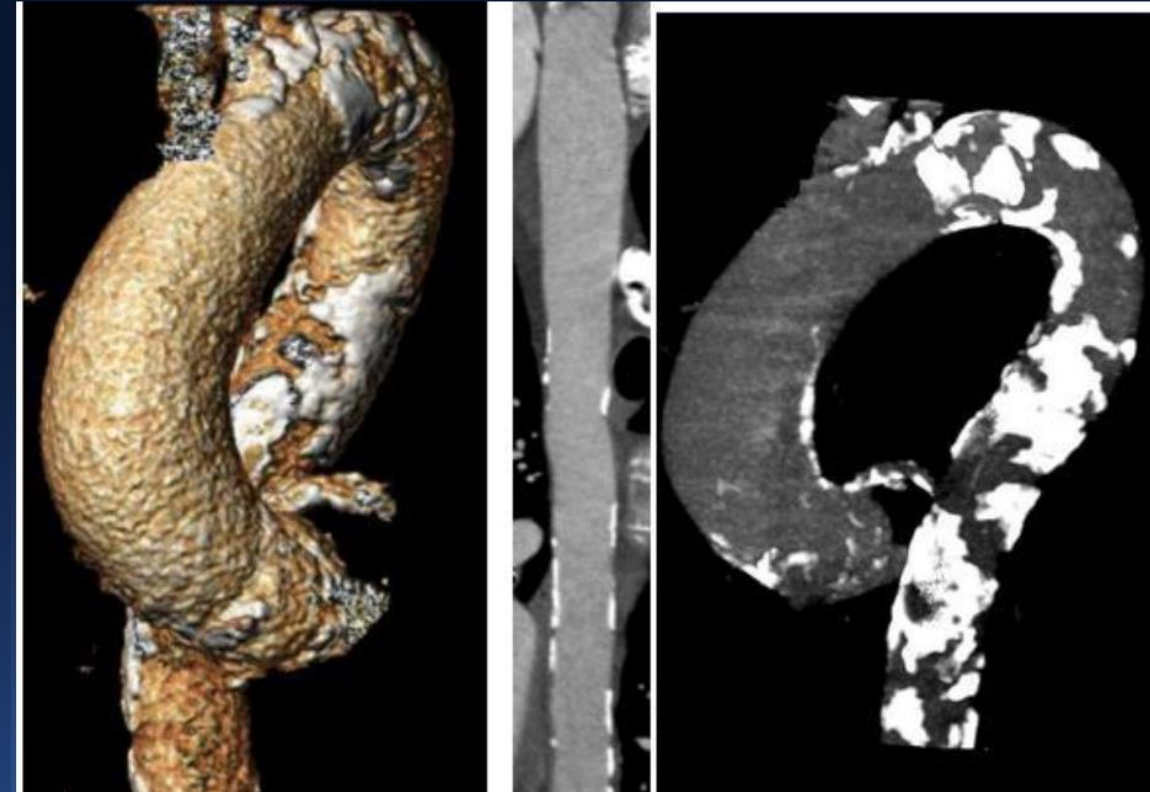
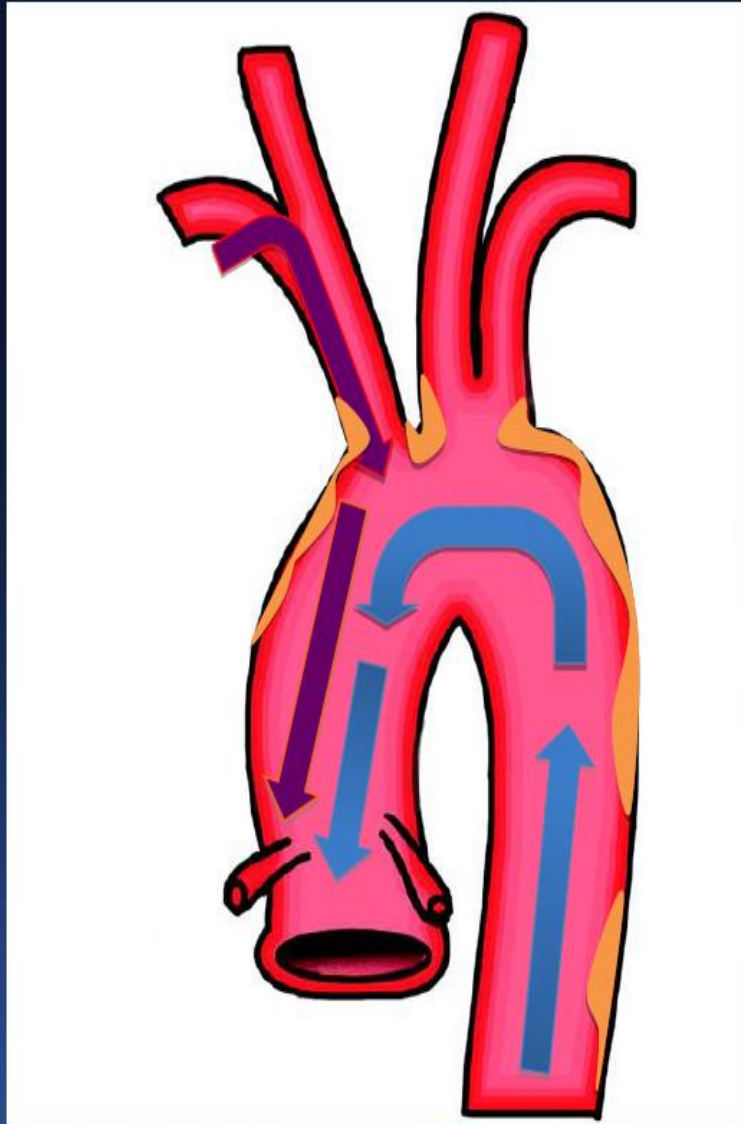
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Disclosure

- Member Advisory Board Keystone Heart
- Consultant DEKRA CE
- Physician Proctor Edwards Lifesciences

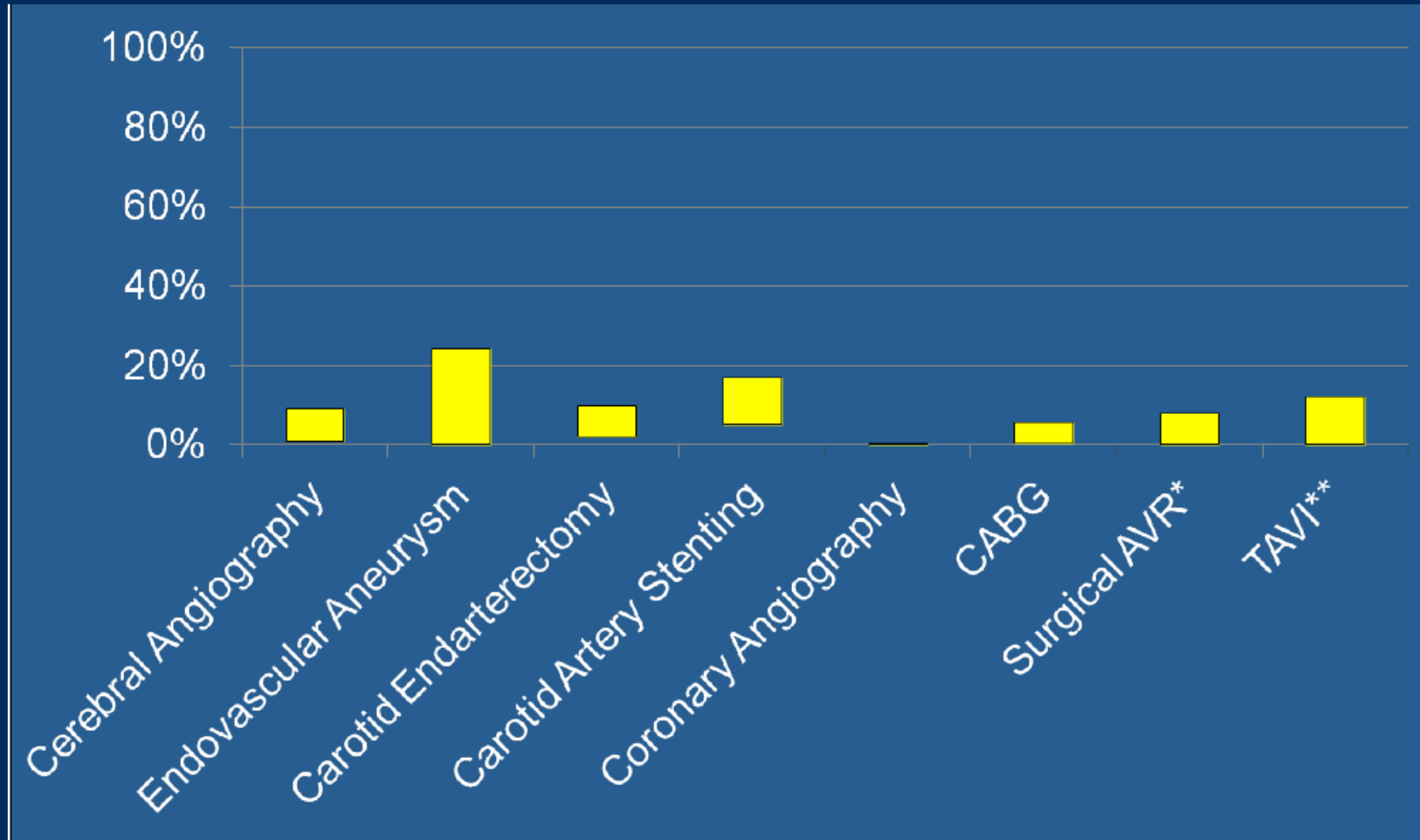
Risk of Catheter-Related Emboli in Patients With Atherosclerotic debris in the Thoracic Aorta



Courtesy of Dr. A. Pacchioni

Karalis DG et al. *Am Heart J*. 1996 Jun;131(6):1149-55.

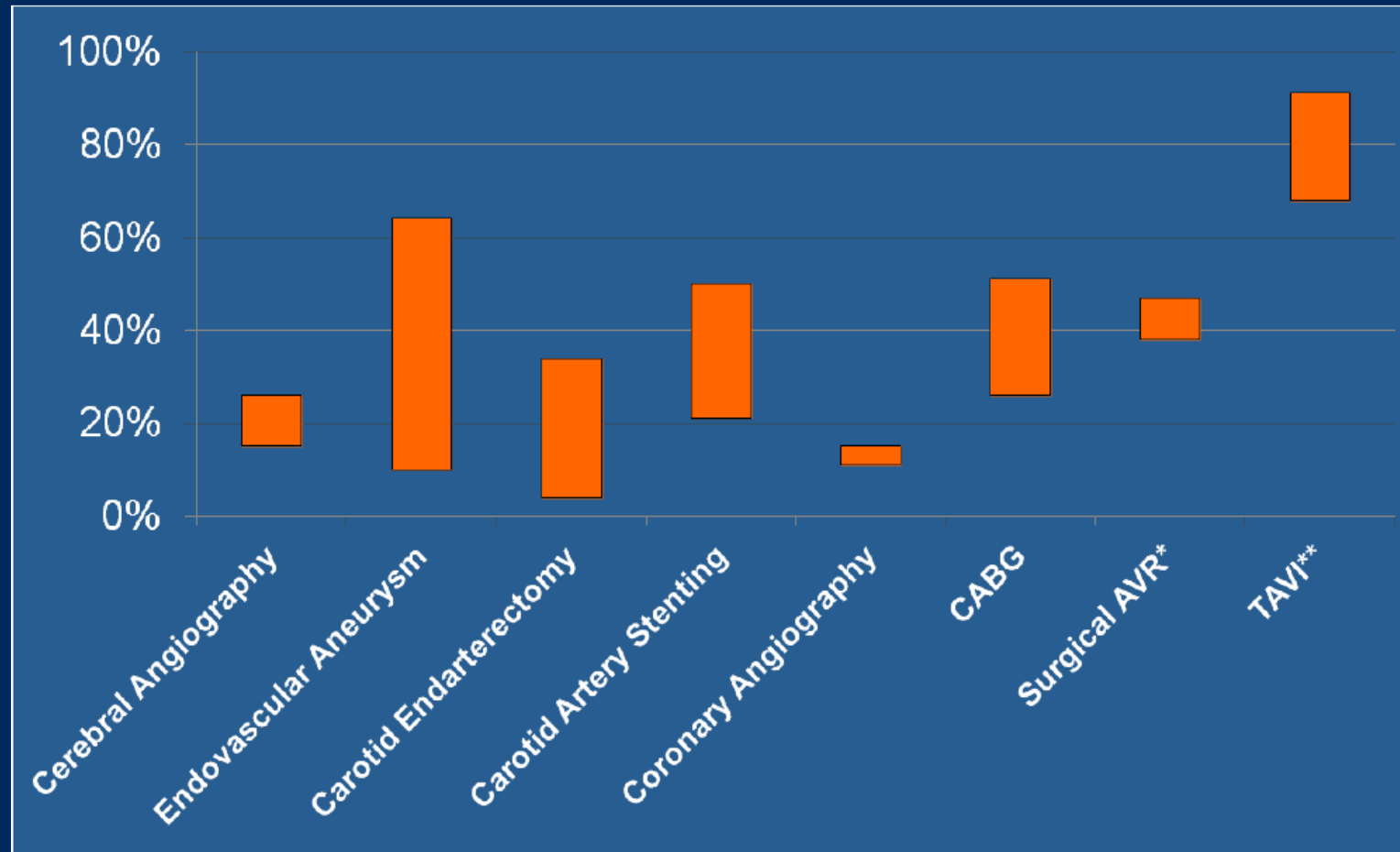
Incidence of Symptomatic Stroke after Invasive procedures



*Stolz 2004, Knipp 2005

** Ghanem 2010, Kahlert 2010

Incidence of New DW MRI Brain Lesions



*Stolz 2004, Knipp 2005

** Ghanem 2010, Kahlert 2010

Estimated Annual US Incidence of New Brain Lesions 2013

Procedure	# of annual US patients		# of annual US patients with new lesions
Coronary angiography		11-17	118.000-182.000
PCI	596.000	11-17	66.000-101.000
CABG	242.000	16-51	39.000-123.000
SAVR	90.000	38-47	34.000-42.000
AF ablation	72.000	8-18	6.000-13.000
TAVR	10.000	68-91	7.000-9.000
Ca endarterectomy	93.000	4-34	4.000-32.000
Ca stenting	70.000	15-67	11.000-47.000
Cerebral angiography	300.000	11-20	33.000-60.000
Endovasc aneurysm	30.000	10-64	3.000-19.000
Total	2.600.000	13-24	321.000-628.000

*Gress- JACC 2012

ACUTE NEUROLOGICAL RISK AFTER BRAIN EMBOLI

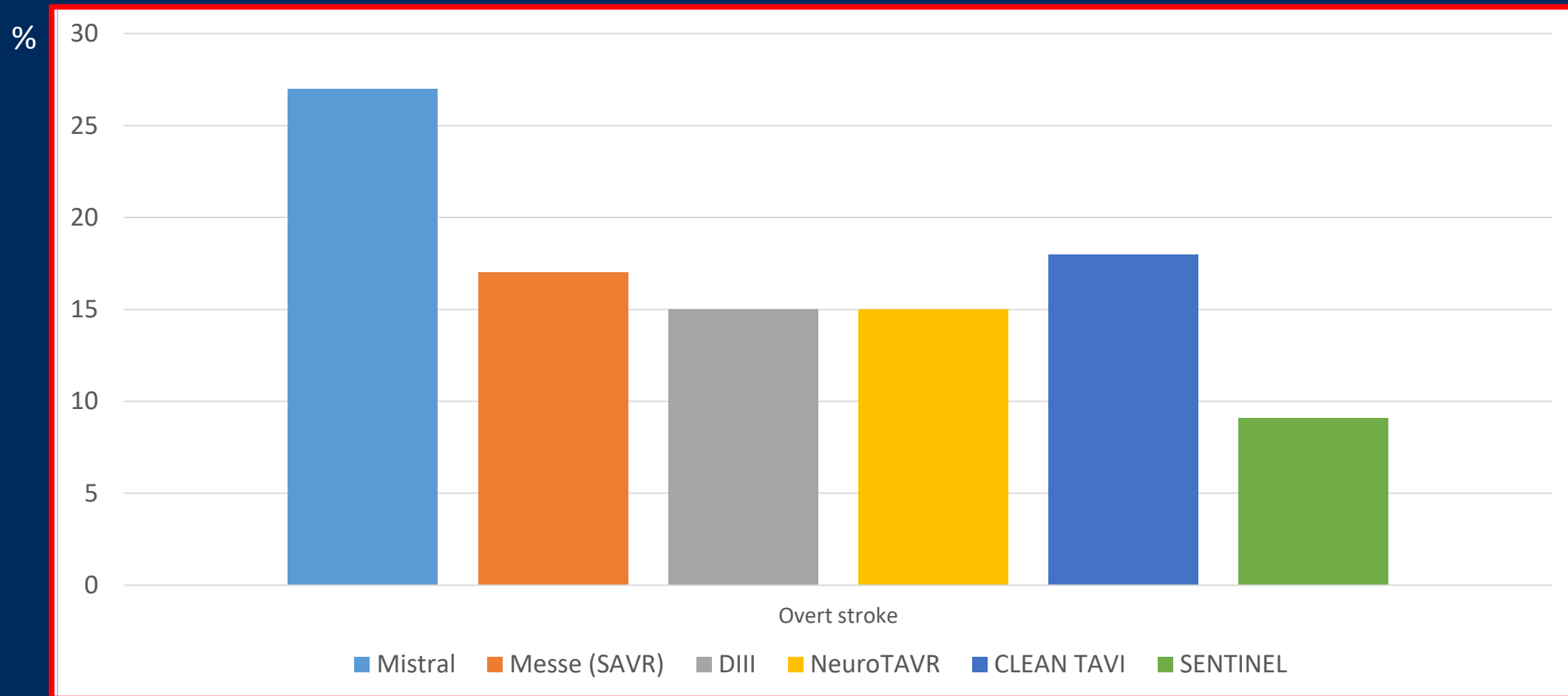
Overt CNS injury; Ischemic stroke, clinical symptoms
>24 hours or <24 hours with imaging confirmation

TIA and delirium without imaging confirmation

Covert CNS injury; imaging findings without
clinical symptoms

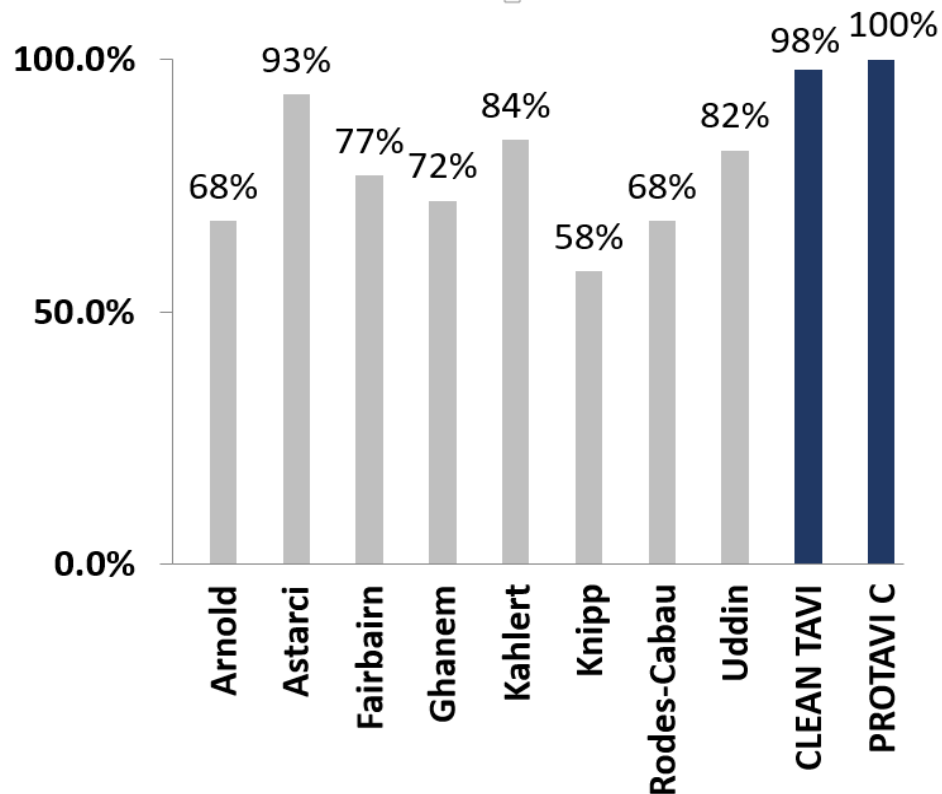
The Incidence of Overt stroke after TAVR; 9-14%

Clinical Symptoms with Imaging findings, neurologists seen each patient



The Incidence of Covert CNS Injury after TAVR

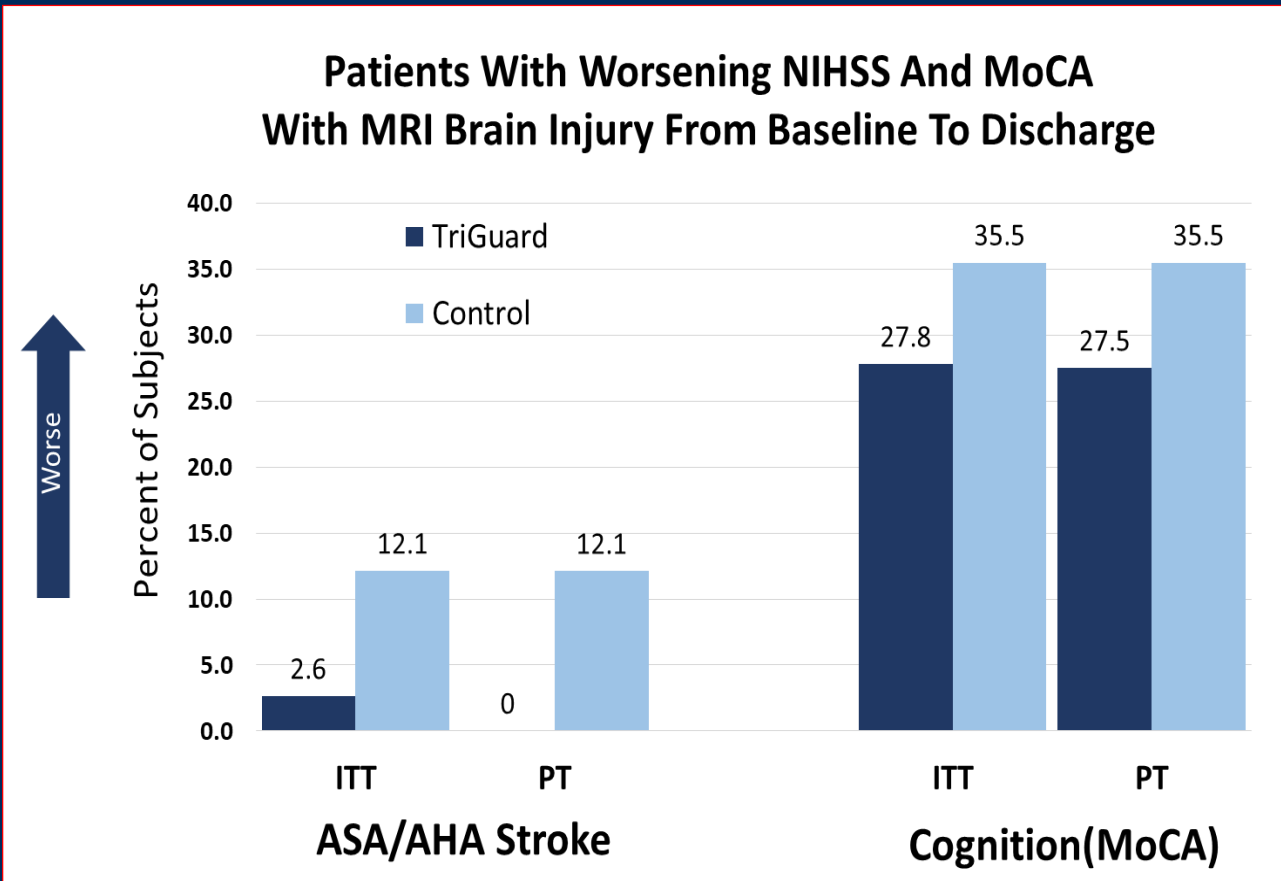
% of Subjects with New Lesions – EU Data



Multiple infarcts (≤ 36 , $\bar{x} = 4.6$)

Considering that about 15% of patients have also clinical symptoms assessed by neurologist, the incidence of covert CNS injury post TAVR is about 60% of all patients.

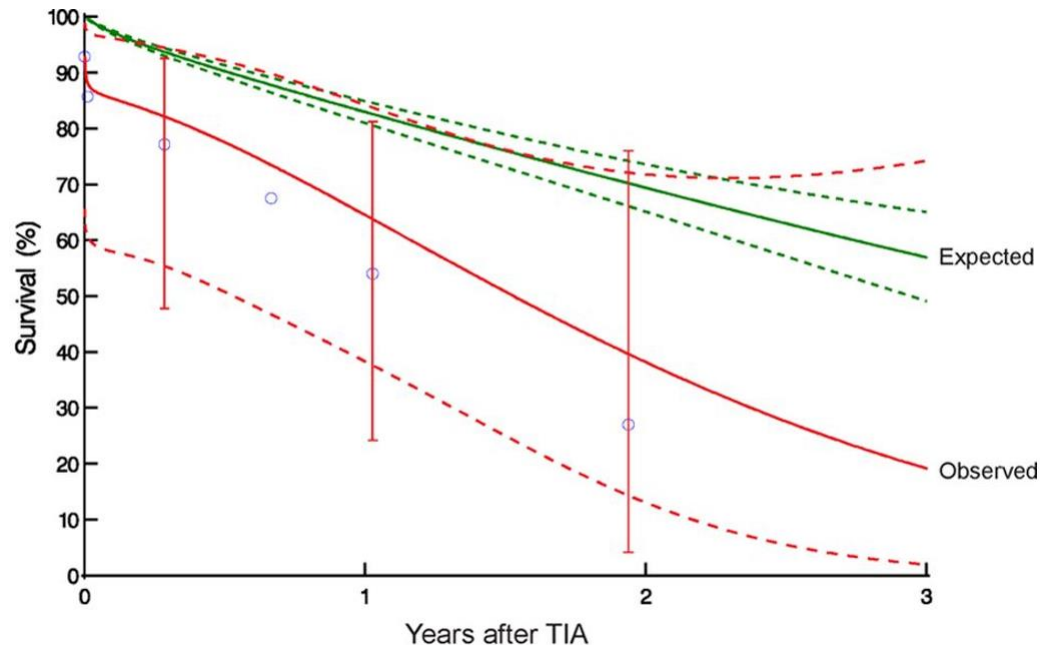
One Out of Three Patients without Cerebral Embolic Protection have Worsening Cognition with new MRI Lesions After TAVR



- The NeuroTAVR data (conducted only in the USA on neurological changes after TAVR without cerebral embolic protection) also demonstrated that
- 33.3% of patient had worse MoCA scores at discharge as compared to baseline
- 40.6% of patient had worse MoCA scores at 30-Days post procedure as compared to baseline

Both TIA and Delirium Increase the Risk of Long-Term Mortality after TAVR

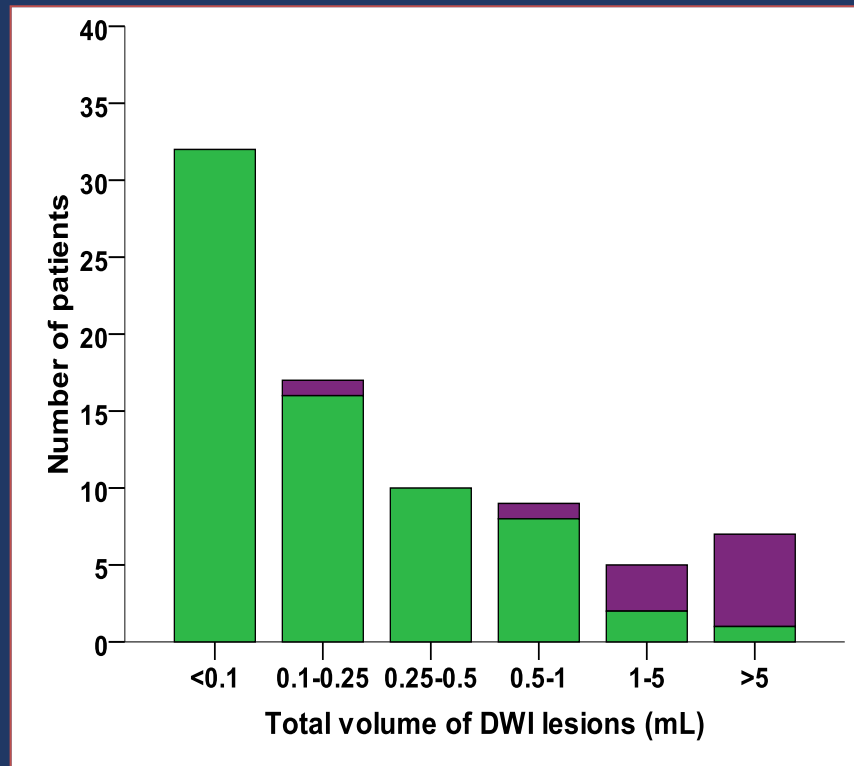
Survival after TIA (Partner trial)



- The incidence of post operative delirium after TAVI is high, 14.5%
- A higher number of DW MRI lesions after TAVI is associated with a higher incidence of postoperative delirium following TAVI*
- Post-op delirium in TAVR patients has been shown to lead to a 3-fold increase in both post-procedural and long-term mortality**
- Post-op delirium can lead to extended length of stay and in-hospital complications as well as an increase in health care costs of between \$16,000 to \$64,000 per patient***

Lesion Volume Correlates with Cognitive Impairment and is Related to Mental Change

Relationship between Volume of Cerebral DWI Lesions and Cognitive Function



Bonati et al. *Lancet* 2010; **375**: 985–997

Patients with acute mental changes have significantly more lesions and larger mean lesion volume compared to patients without acute post-procedural mental changes

Choi et al 2000 N=30	Mean lesion volume (mL = cm3)
Patients with new mental change	0.53 (0.12-2.4)
Patients with no mental change	0.23 (0.07-0.41)

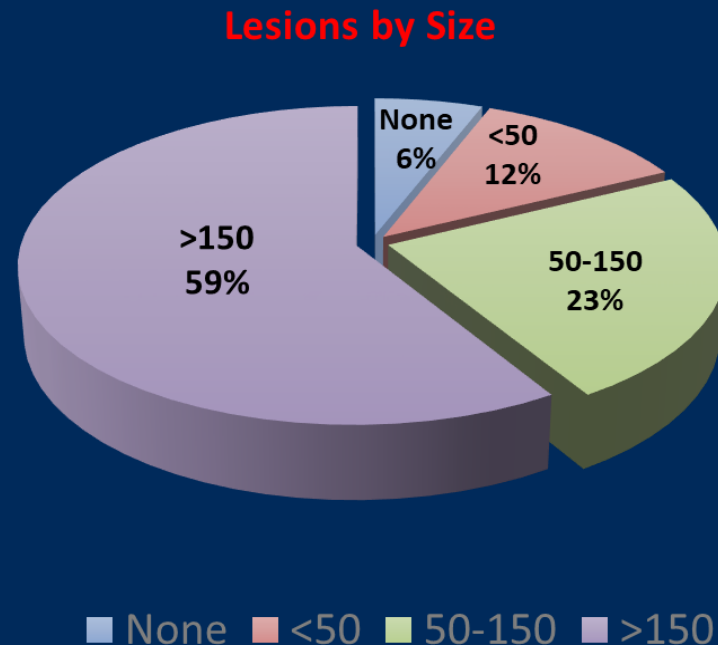
Choi SH et al. *Neurology*. 2000;54(1):83-89

Long term Consequences of Decreased Brain Reserve – Loss of Brain Tissue

On average 294.7 mm³ loss of brain tissue, each NeuroTAVR patient lost potentially during the unprotected TAVI procedure:

23.6 Million Neurons and 1.33 Billion synapses

(10 MAY 2013 VOL 340 SCIENCE).



Reduced brain reserve increases the risk of:

- dementia
- depression
- Parkinson's disease
- Alzheimer's disease, and
- overall neuro-cognitive decline

In addition, after TAVR clinically silent brain infarcts are associated with

- over 2 fold increase of dementia and
- over 3 fold increase of a clinically evident stroke

Restrepo, L. et al Stroke 2002; 33:2909 – 2915, Lund C., et al. EHJ 2005, Vol 26 (13):1269-1275, Messe SR et al. Circulation 2014;129:2253-61., Miller DC, et al. J Thorac Cardiovasc Surg. 2012;143:832-843 e813, Schwarz et al. Am Heart J. 2011 Oct;162(4):756-63. Knipp SC et al. Ann Thorac Surg 2008;85:872-9., Vermeer, S. et al. N Engl J Med 2003; 348:1215-1222 March 27, 2003 DOI: 10.1056/NEJMoa022066, Vermeer, S., et al. Stroke 2003; 34:1126-1129

Summary –

- Multiple CV treatments have a risk of brain emboli.
- Brain lesions impact Brain function !
- TAVR now “under investigation”, but not the only cause!
- Need to focus to minimize all adverse events, especially cerebral damage, while further advancing patient care.